



March 16, 2004

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OFFICE OF SPECIAL NUTRITIONAL PRODUCTS  
LABELING AND DIETARY SUPPLEMENTS  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration (HFS 800)  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

RE: Notification for Certain Types of Statements on Dietary Supplements

Dear Sir or Madam:

As required by Section 403(r)(6)(c) of the Food, Drug and Cosmetic Act, Pharmanex, LLC, 75 West Center Street, Provo, Utah 84601, intends to market a dietary supplement product with the following label and marketing statements on nutritional support:

Products: Nutrimune Chews™

Statements:

Nutrimune Chews™

- Delicious immune protection
- Adults and children alike will enjoy these tasty vanilla-caramel chews that protect and strengthen their bodies
- Delicious treat that helps support healthy immune function and healthy bones
- Provides a stable, standardized concentrate of immune-enhancing proteins in the form of Colostrum MFT™
- Clinical studies have identified that colostrum enhances the systemic immune response and reinforces the body's ability to defend itself
- Contains immunoglobulins (IgG), the bioactive proteins contained in colostrum that are essential components of an optimally functioning immune system
- Promotes strong healthy bones by supplying calcium, plus vitamin D, which assists in calcium absorption

We certify that the information contained in this notice is complete and accurate and that Pharmanex®, LLC, has substantiation that these statements are truthful and not misleading.

Sincerely,

Mark Bartlett, Ph.D.  
Senior Scientist  
Pharmanex® Research and Development

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